Notice of Allowability	Application No.	Applicant(s)	
	10/082,691	DONOVAN, STEPHEN	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *amendment filed 5/27/05*.

2. ☒ The allowed claim(s) is/are *1-4,6,7,12,17,18 and 22-26*.

3. ☐ The drawings filed on _____ are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

SJD

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The title of the invention was changed to:

--A method for treating neurogenic inflammation pain with botulinum toxin and substance P components--.

Claims 8 and 19 were cancelled.

All of claims 1-4, 6-7, 12, 17-18 and 22-26 of record are replaced with the following claims:

--1. A method for treating neurogenic inflammation pain, the method comprises injecting a therapeutically effective amount of about 0.01 units to about 1,000 units of an agent to a patient, the agent comprising the light chain of a botulinum toxin covalently coupled to the H_N portion of the heavy chain of the botulinum toxin, and a substance P component covalently coupled to the botulinum toxin H_N portion, the substance P component being effective in binding to a substance P receptor, thereby treating the neurogenic inflammation pain for at least about two months.

2. The method of claim 1 wherein the botulinum toxin light chain is the light chain of a botulinum toxin selected from the group consisting of botulinum toxin serotype A, serotype B, serotype C, serotype D, serotype E, serotype F and serotype G.

3. The method of claim 1 wherein the botulinum toxin H_N portion is the H_N portion of a botulinum toxin selected from the group consisting of botulinum toxin serotype A, serotype B, serotype C, serotype D, serotype E, serotype F and serotype G.

4. The method of claim 2 wherein the light chain is a light chain of a botulinum toxin serotype A.

6. The method of claim 3 wherein the H_N portion is an H_N portion of a botulinum toxin serotype A.

7. The method of claim 1 wherein the substance P component is substance P.

12. The method of claim 1 wherein the pain is arthritis pain.

17. The method of claim 1 wherein the agent is injected subcutaneously.

18. The method of claim 1 wherein the agent is injected intramuscularly.

22. The method of claim 1 wherein the agent is injected in an amount from about 10^{-2} U/kg to about 100 U/kg.

23. The method of claim 1 wherein the agent is injected in an amount from about 10^{-1} U/kg to about 10 U/kg.

24. The method of claim 1 wherein the agent is injected in an amount from about 1 unit to about 20 units.

25. The method of claim 1 wherein the agent is injected in an amount from about 1 unit to about 10 units.

26. The method of claim 1 wherein the agent is injected in an amount from about 0.1 U/kg to about 30 U/kg.--

Authorization for this examiner's amendment was given in a telephone interview with Mr. Hollrigel on August 18, 2005.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx
Primary Examiner
Art Unit 1651